

**REMARKS**

Claims 1-54 are currently pending in the instant application. The claims remain rejected under 35 U.S.C. §102, §103, and obviousness-type double patenting, responses to which are discussed below. Applicants have amended several claims and added new claims, as is discussed below. No new matter has been added by these changes.

In response to the Final Office Action dated March 7, 2003, Applicants submitted a Reply with amendments dated June 16, 2003. The amendments were not entered pursuant to an Advisory Action dated July 8, 2003. Applicants then received a Notice of Abandonment dated October 22, 2003, which referenced a telephonic interview between the Examiner and the undersigned. Applicants acknowledge the interview, where the undersigned was informed that the application was to be considered abandoned. Applicants advised the Examiner that a Petition to Revive with a Request for Continued Examination would be filed.

This Reply is to be considered in response to the rejections set forth in the Final Office Action dated March 7, 2003. Applicants request that the amendments presented in the Reply dated June 16, 2003 not be entered.

Applicants acknowledge and appreciate the Examiner's favorable reconsideration and withdrawal of the previous rejection of claim 5 under §112.

Claim 1 has been amended to more particularly define what the Applicants regard as their invention. The "particle forming composition" has been amended to recite a composition that incorporate into the claim the definition of a "particle forming composition" and "particle", as defined on page 4, lines 17-23. Similarly, claims 36-38, and 40-42 have been amended to refer to a composition of non-crystalline particles and a composition of claim 1 rather than a "particle forming composition".

Claim 19 has been amended to provide the proper Markush form, by inserting “or” in place of “and”.

Claims 34 and 35 have been amended to more particularly point out what the Applicants regard as their invention, namely, that the unit dose comprises 200 and 100 mg of a modafinil compound, respectively.

Claim 44 has been amended to provide the proper Markush form, by inserting “or” in place of “and”.

New claims 55-57 have been added to further delineate the modafinil compound as its levorotatory isomer. Support for this amendment can be found on page 1, lines 30-34.

New claim 58 have been added to further delineate the modafinil compound as modafinil. Support for this amendment can be found on page 1, lines 15-16.

**Rejections under 35 U.S.C. §102(b)**

***Grebow:***

Claims 1-4, 6, 32, 33, 36, 37, 39, 41-44, 47, 48, and 51 remain rejected under 35 U.S.C. §102(b) as being anticipated by Grebow et al. The Office Action alleges that Grebow teaches particles, and that the “forming” language does not carry patentable weight.

Applicants disagree with the assertion that the “forming” language does not carry patentable weight. Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation (*see* MPEP §2111.02). The phrase “particle forming composition” is clearly set out as specialized term in the specification, and it is defined therein (*see* page 4, lines 17-19). Hence, Applicants submit that the limitation of the phrase is necessary to give “life, meaning and vitality” to the claim, and as such, should be regarded as carrying patentable weight.

However, in order to expedite prosecution of the application and to define the invention with no intent to alter the scope of the claims in any way, Applicants have amended claim 1 to replace “particle forming composition” and “particle” with their respective definitions. Hence, newly amended claim 1 is drawn to a composition comprising a modafinil compound wherein said composition forms non-crystalline particles of the modafinil compound upon contact with an aqueous medium. Claims 36, 41 and 42 have been amended to refer to compositions of non-crystalline particles and to compositions of claim 1.

Newly amended claim 2 has been modified to refer to aqueous compositions comprising non-crystalline particles of a modafinil compound.

Applicants respectfully submit that Grebow teaches various particle sizes of *crystalline* modafinil. Indeed Figures 2-5 of the reference show pictures of boulder-type crystalline structures of modafinil. Hence, Grebow does not teach the formation of *non-crystalline* particles. Since Grebow does not teach all the elements of the instant claims, Applicants respectfully submit that newly amended claims are novel over Grebow.

Hence, Applicants respectfully request entry of the amendments and remarks, and reconsideration and withdrawal of the novelty rejection with respect to Grebow.

***Nguyen:***

Claims 1-4, 6, 7, 11, 14, 15, 32, 33, 36, 37, 39, 47, 51, and 54 remain rejected under 35 U.S.C. §102(b) as being anticipated by Nguyen et al. The Office Action alleges that Nguyen teaches compositions that contain particles or microparticles of an active ingredient, and that the “forming” language does not carry patentable weight.

Similar to the argument presented above, Applicants respectfully submit that the preamble indeed carries patentable weight. Furthermore, Nguyen teaches the preparation of aqueous “pasty mixtures” which are to be extruded and lyophilized (see Abstract). There is

no reference to the formation of *non-crystalline* particles. Since Nguyen does not teach all the elements of the instant claims, Applicants respectfully submit that newly amended claims are novel over Nguyen.

Hence, Applicants respectfully request entry of the amendments and remarks, and reconsideration and withdrawal of the novelty rejection with respect to Nguyen.

**Rejection under 35 U.S.C. §103(a)**

Claims 17, 18, 34, 35, 38, 45, 46, 49, 50 and 53 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Grebow, et al., and claims 8-10, 13, 17-20, 34, 35, 38, and 40-46 are similarly rejected over Nguyen, et al. in view of Lafon.

Applicants respectfully submit, for the reasons stated above, that the references, either alone, or in combination, fail to teach the subject matter of the instant claims. Applicants further submit that Lafon does not cure the deficiencies of Nguyen, since it fails to teach the formation of *non-crystalline* particles. Since neither Grebow, nor Nguyen in view of Lafon teach the disclosure of the instant application, Applicants respectfully submit that the instant claims are non-obvious.

Hence, Applicants respectfully request entry of the amendments and remarks, and reconsideration and withdrawal of the rejections under §103.

**Double Patenting Rejection**

Claims 1, 3-5, 14-15, 32-34 and 35 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3, 7, 8, 10-13, and 26-29 of co-pending Application No. 09/974,473.

Co-pending application No. 09/974,473 has now issued as U.S. Pat. No. 6,489,363.

Applicants submit that the instant claims are not obvious in view of the '363 patent. The '363 patent teaches *solutions* of modafinil compounds, where the modafinil compounds are *dissolved* in solution. There is no teaching in the '363 patent that the modafinil compounds form *non-crystalline* particles. Since the '363 patent does not teach the disclosure of the instant application, Applicants respectfully submit the instant claims are not obvious over the '363 patent.

Hence, the double patenting rejection is improper, and Applicants respectfully request withdrawal of the rejection.

**Conclusion**

In view of the above, it is requested that the amendments and remarks be entered. It is believed that all the claims are in form for allowance, and an early notification to that end is respectfully requested. Applicants invites the Examiner to contact the undersigned at (610) 738-6465 to clarify any unresolved issues raised by this response.

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Respectfully submitted,



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